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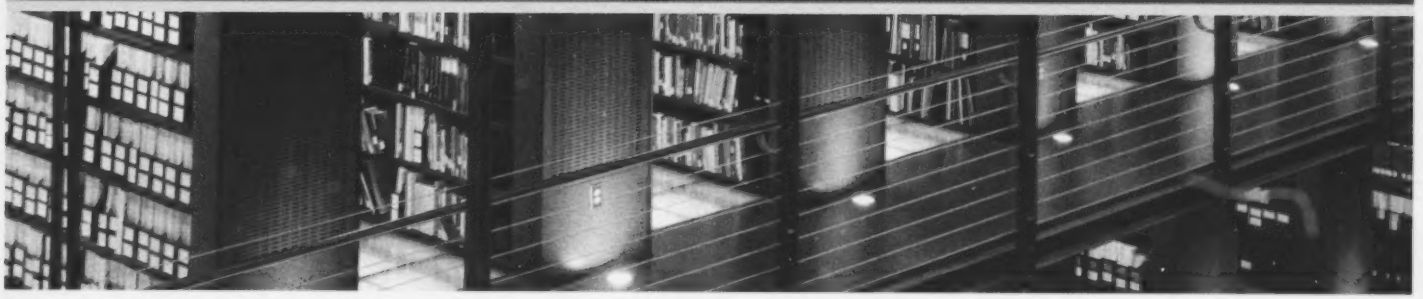

Organ Donation and Transplantation in Canada

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Parliamentary Information and Research Service

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(Background Paper)

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ORGAN DONATION AND TRANSPLANTATION IN CANADA*

1 INTRODUCTION

Despite an increase in the organ donor rate in Canada, the waiting list of Canadians in need of an organ transplant continues to grow. This paper will provide an overview of organ donation and transplantation across Canada, discuss some of the statistics involved and list some of the options for increasing the donor rate.

2 BACKGROUND

In 1999, two reports highlighting concerns about a persistent and growing gap between the supply of and demand for organs and tissues for transplantation in Canada were issued, one by the House of Commons Standing Committee on Health and the other by the National Coordinating Committee on Organ and Tissue Donation, Distribution and Transplantation.[1]

In April 2001, the Government of Canada announced the creation of the Canadian Council for Donation and Transplantation (CCDT), which would be an advisory body to the Conference of Deputy Ministers of Health in support of efforts by the Conference to coordinate federal, provincial and territorial activities relating to organ donation and transplantation. The CCDT conducted extensive consultations on standards and clinical practice guidelines and made recommendations on the issues of cardiac death, severe brain injury, immunological risk following transplant and medical management to optimize donor organ potential.

In October 2007, the deputy ministers of health for the provinces (except Quebec) and territories agreed that the CCDT's functions would be transferred to Canadian Blood Services and that Canadian Blood Services would assume responsibility for Canada's organ and tissue donation and transplantation system. On 12 August 2008, Canadian Blood Services announced that it had merged with the CCDT and that its mandate would be expanded beyond blood to include organs and tissues.[2] (In Quebec, the organization mandated to coordinate organ donation is Transplant Québec. Its mission includes both optimizing the availability of organs and coordinating their procurement and allocation.[3])

3 TRENDS, STATISTICS AND COMPARISONS

When considering the trends and statistics in organ donation, as well as when making comparisons of these figures among jurisdictions, it is important to keep a number of variables in mind. A low donor rate, for example, may be more reflective of lower rates of injury and better health care interventions than it is of a lack of altruism or poor recruitment of donors. Similarly, an ever-growing waiting list for organ transplant may indicate that patients are surviving longer while waiting than they once did, rather than a worsening supply of organs for transplant. The following is a discussion of

Canada's performance in organ donation and transplantation in recent years and how that performance compares with that of other nations.

3.1 Definitions

Before defining donor rate, it is important to explain that there are different types of donors. For the purposes of this document, the following definitions apply:

- Intended donor – An individual who has indicated a desire to become a donor upon death or, when appropriate, during life.
- Potential donor – An individual identified within a health care facility as being appropriate to pursue as a donor; includes those individuals from whom organs may have been procured but not allocated or transplanted.
- Actual donor – An individual from whom at least one organ has been procured, allocated and successfully transplanted.
  - Deceased donor – An individual who becomes a donor following death, either brain death[4] or cardiac death.
  - Living/live donor – An individual in good health who donates to a recipient.

3.2 Organ Donation Rates

3.2.1 Deceased Organ Donors in Canada

According to the Canadian Institute for Health Information (CIHI), the deceased donor rate in Canada increased by 42% between 2007 and 2016, from 14.7 to 20.9 donors per million population (PMP), which translates to 485 deceased donors in 2007 and 758 deceased donors in 2016.[5] Each deceased donor can provide up to eight organs,[6] although the average number of organs used for transplantation is lower.[7]

In large part, donations from deceased donors come after brain death, the traditional criterion to determine death. Brain death is referred to as "neurologically determined death," or NDD, by CIHI. However, since 2006, donors have been recruited under certain circumstances after cardiac death. Cardiac death is referred to as "cardiorespiratory determined death" or DCD, by CIHI. (Cardiac death is discussed further in section 3.3, "Identifying the Donor Pool.")

The number of deceased donors in this new category has increased steadily since 2006, when there were four DCD donors, only from Ontario. By 2010, all jurisdictions, except Manitoba and Saskatchewan, were considering DCD donors, and 45 DCD donors were obtained that year.[8] Since that time, all provinces have been equipped to recruit DCD donors. In 2016, this category accounted for almost 25% of all deceased donors.

3.2.2 Living Organ Donors in Canada

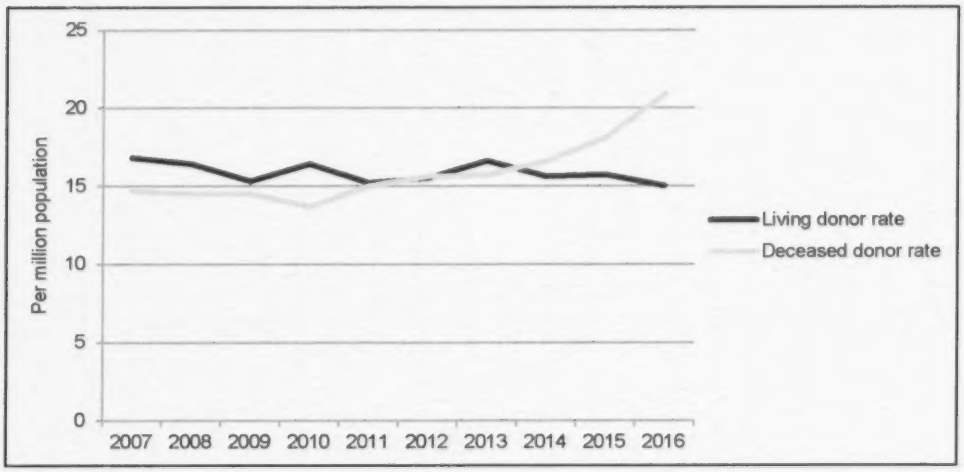
Some organs can be donated from live donors. Living donors can provide a single kidney, a partial liver (lobe), a single lung, or a partial intestine or pancreas (segment or islet cells).

Between 2003 and 2012, the number of living donors in Canada grew from 435 to 539, and until 2011, was greater each year than the number of deceased donors.[9] In 2012, the living and deceased donor rates were identical, at 15.5 PMP, but since that time, the living organ donor rate has remained at between 15.0 and 16.6 PMP and has been overtaken by the rising deceased organ donor rate.[10] These trends are illustrated in Figure 1.

Figure 2 illustrates the trends in the number of NDD and DCD donors and the number of living donors in Canada, from 2012 to 2016.

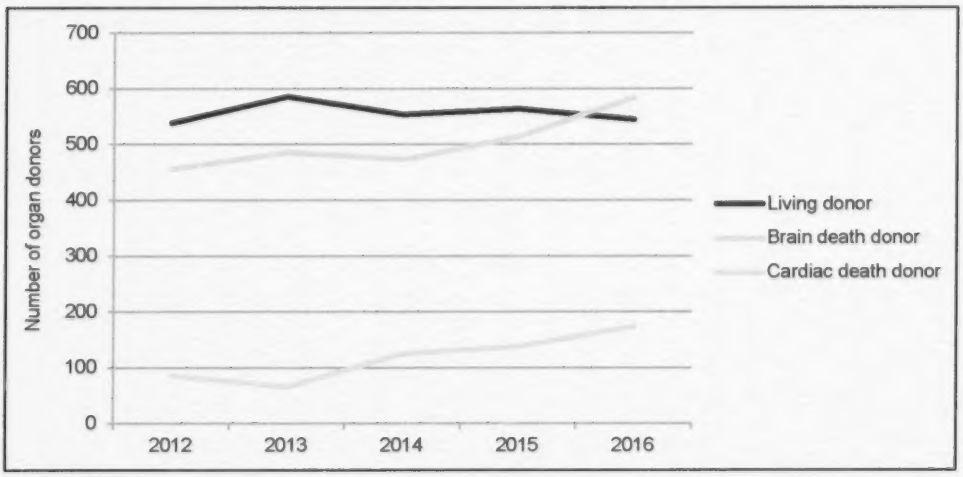
Figure 3 shows the living and deceased organ donor rates across Canada in 2016.

Figure 1 – Organ Donor Rates in Canada, 2007–2016



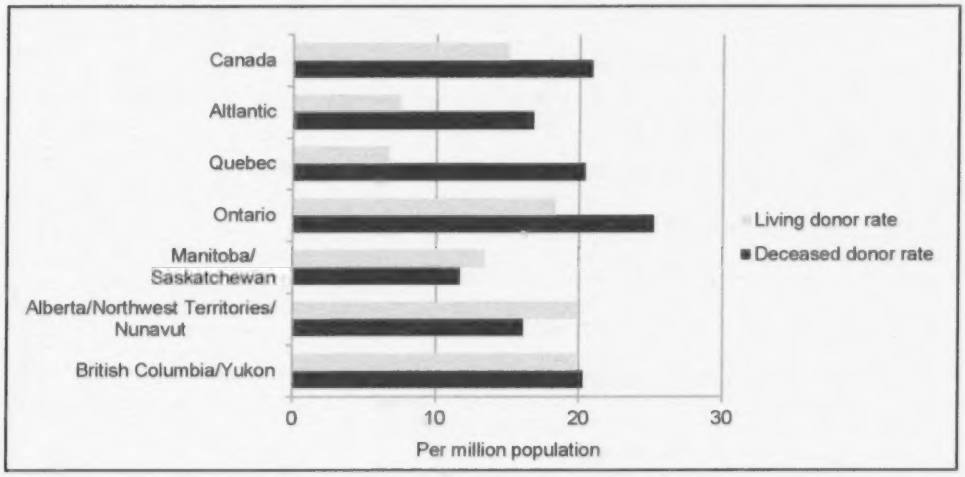
Source: Figure prepared by the author using data obtained from Canadian Organ Replacement Register [CORR] of the Canadian Institute for Health Information, "Figure 23: Donor rate per million population, by donor source, Canada, 2007 to 2016," "Treatment of End-Stage Organ Failure in Canada, Canadian Organ Replacement Register, 2007 to 2016: Data Tables, Donors," *CORR Annual Statistics, 2007 to 2016*.

Figure 2 – Total Number of Organ Donors in Canada, by Type, 2012–2016



Source: Figure prepared by the author using data obtained from Canadian Institute for Health Information, "Table 4: Deceased organ donor type over time, by province/region, Canada, 2012 to 2016," *e-Statistics Report on Transplant, Waiting List and Donor Statistics: 2016 Summary Statistics, January 1 to December 31, 2016*.

Figure 3 – Organ Donor Rates Across Canada, by Region, 2016



Source: Figure prepared by the author using data obtained from Canadian Institute for Health Information, "Figures 23–25. Donor rate," "Treatment of End-Stage Organ Failure in Canada, Canadian Organ Replacement Register, 2007 to 2016: Data Tables, Donors," *CORR* [Canadian Organ Replacement Register] *Annual Statistics, 2007 to 2016*.

3.2.3 Comparing Canada's Donor Rates to Those of Higher Performing Countries

International comparisons of deceased organ donor rates reveal that Canada is not among the highest performers worldwide, although it is usually among the top third of ranked countries. In 2016, Canada ranked 19th among 68 countries for deceased organ donor rate with a rate of 20.1 PMP. The top five countries were Spain (43.4 PMP), Croatia (38.6 PMP), Portugal (32.6 PMP), Belgium (31.6 PMP) and the United States (U.S.) (31.0 PMP).[11]

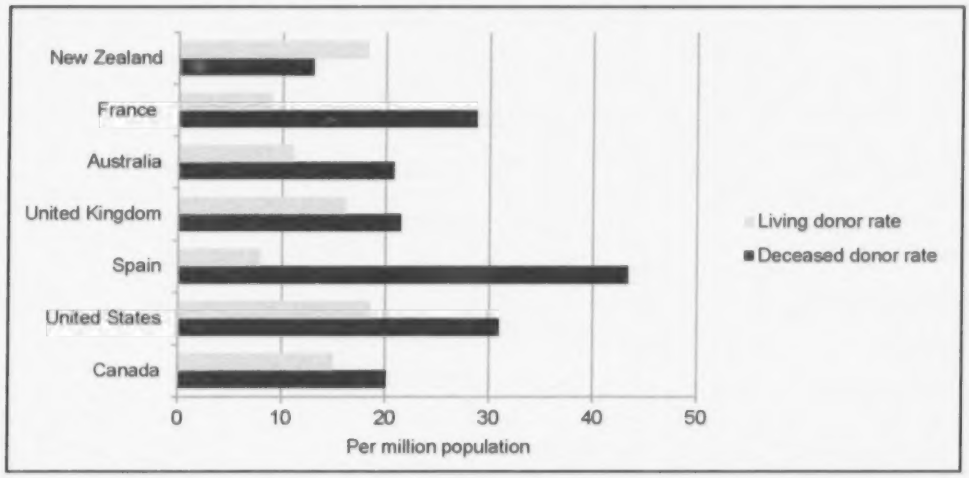
However, Canada ranks a little better for recruiting living donors than it does for recruiting deceased donors. Data in the same report indicate that Canada ranked 14th for living organ donors, with a rate of 15 PMP. In comparison, Turkey ranked first, at 45.8 PMP. The United States had a higher live donor rate than Canada, at 18.6 PMP, while, Spain performed relatively poorly at less than 8 PMP.[12]

The disparity among donor rates can be ascribed to a number of factors. In addition to the specific organ donation and transplantation practices of each country, social, demographic and mortality characteristics can have an impact on the organ donor rate. As well, the definition of "donor rate" can vary from one country to another. For example, some countries include in their calculations those instances in which a donor is identified but ultimately no organ is transplanted into a recipient.[13] This definition would inflate donor numbers relative to Canada, where "donor rate" includes

only actual donors from whom at least one organ has been procured and successfully transplanted.

Figure 4 provides comparative data of living and deceased organ donor rates in selected countries.

Figure 4 – Organ Donor Rates, Selected Countries, 2016



Source: Figure prepared by the author using data obtained from International Registry in Organ Donation and Transplantation, *Final Numbers 2016*, December 2017.

3.3 Identifying the Donor Pool

There is a tendency to count all members of the general population as "potential donors." However, this is somewhat misleading, because few individuals will ever be in the situation of being considered for organ donation upon their death. Proponents of donor registries (databases containing the names of individuals who wish to donate their organs after death) suggest that such databases better reflect the donor pool. As with the general population, this is not strictly true, because the number of individuals who ultimately become available as possible donors ("potential donors") is a small fraction of those who may be interested in becoming a donor ("intended donors").

Potential deceased organ donors are identified from within the very limited pool of individuals whose death fulfills specific criteria. As mentioned above, this has traditionally meant that the individual would have succumbed to brain death, or NDD. Brain deaths are often the result of such incidents as trauma from a motor vehicle accident or a gunshot wound or a cerebrovascular accident, such as a stroke. The pool of potential donors has expanded slowly in recent years to include cardiac death, or DCD. However, the cardiac death must occur in a hospital, which is equipped to follow the candidate as a potential organ donor. Finally, within this limited pool, the number of candidates may further be reduced because of age. While there is no specific age cut-off in Canada, over the years, there has been a tendency to limit eligibility to individuals under a given age. However, the number of older organ

donors has increased recently, as candidates are assessed on a case-by-case basis.[14]

In 2006, some provinces began to expand the eligibility criteria for the type of death following which organs could be donated. Information from CIHI indicates that in 2006, Ontario and Quebec were the first provinces to consider individuals who succumbed to cardiac death, or DCD, as organ donor candidates. Now, all jurisdictions in Canada consider organ donation following DCD. According to a recent study, the acceptance of organs following DCD in Ontario has expanded the donor pool and increased overall transplant activity.[15]

Circumstances that could result in organ donation after DCD include cardiac arrest in someone already brain dead, unsuccessful resuscitation of a person in cardiac arrest, and cardiac arrest following withdrawal of treatment in the intensive care unit. The last is referred to as "controlled" DCD because preparations for organ removal and preservation can be initiated before the donor's death, thereby controlling the timing of the withdrawal of treatment.[16]

3.4 Use of Donated Organs

In 2016, 1,302 individuals, living and deceased, donated organs in Canada, and 2,906 organs were transplanted. This represented 331 more organs than were transplanted in 2015, and 775 more than in 2011. Over half of the transplanted organs were kidneys (1,731), followed by livers (579), lungs (302), hearts (202) and pancreases (92).[17] The average number of organs used for transplantation from deceased donors, where multiple organs are available for transplant, fluctuated between 3.4 and 3.8 from 1999 to 2008.[18]

3.5 Non-use of Organs

As already discussed, Canada does not include in its donor rate calculations potential donors whose organs were not used (either because the organs were not recovered or because they were not transplanted). There are numerous reasons why organs are not used, only some of which can be controlled and possibly targeted as areas through which organ donor rates could be improved. For example, organ damage or other anatomical damage, and poor organ function are reasons for non-use that cannot be overcome, but logistical problems experienced by the donation and transplant teams, and failure to search for or locate potential recipients are circumstances that could be addressed.

The logistical issues and identification of compatible recipients could be improved with an information management system like the real-time national waiting list operated by the private, not-for-profit United Network for Organ Sharing (UNOS) in the United States[19] through the Organ Procurement and Transplantation Network (OPTN). Created under the *National Organ Transplant Act* of 1984, the OPTN links all professionals involved in the donation and transplant system by maintaining the national waiting list and allocating donated organs on an "equity basis."[20] All U.S. transplant centres and organ procurement organizations are members of the

OPTN. (The U.S. national waiting list is discussed in greater detail in section 5.1, "Registries," in this paper.)

3.6 Transplants and Candidates Awaiting Transplants

In 2016, 256 Canadians died waiting for an organ, and at the end of the year, 4,469 people were awaiting an organ transplant. These figures had dropped slightly from 2015, when 261 people died, and 4,587 people awaited transplants at the end of the year.[21]

Although Canada's living donor rate is higher than that of many countries, the need for organs cannot be addressed by this group alone, since living donors are not permitted to donate many organs. As long as there is a gap between the number of organs available for transplant and the number of organs needed, there will be a need to explore options for increasing both the deceased and living donor rates.

4 ORGAN AND TISSUE DONATION AND TRANSPLANTATION REGULATIONS

In December 2007, federal regulations for organ and tissue donation and transplantation came into effect. Health Canada indicated that the purpose of the new regulations was "to minimize the potential health risks to Canadian recipients resulting from transplantation."[22] The *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* standardize the screening and testing of potential donors in Canada and are described as reflecting the best practices already in place across the country.[23]

The regulations require that the procuring health care facility do the following to determine donor suitability:

- obtain donor information and history;
- perform a physical exam of the donor;
- perform certain tests for disease and disease agents; and
- ensure that the donor is not unsuitable to donate on the basis of exclusionary criteria (described below).

The regulations incorporate by reference the *Cells, Tissues, and Organs for Transplantation and Assisted Reproduction: General Requirements* ("the general standard"), a document prepared by and available from the CSA Group (previously known as the Canadian Standards Association). The regulations stipulate that the general standard provides the criteria for determining donor suitability and establishes exclusionary criteria for:

- death from unknown causes;
- infection from a prion disease, such as Creutzfeldt-Jakob disease or encephalitis;
- affliction with dementia; and

- infection, or a high risk of infection, with HIV, viral hepatitis or rabies.

Annex E to the general standard expands on the category of individuals at risk for HIV and viral hepatitis, primarily hepatitis B and C (HBV and HCV). The exclusionary criteria listed in the annex are the following:

- men who have had sex with men in the preceding five years;
- persons who have used intravenous, intramuscular or subcutaneous drugs in the preceding five years;
- persons with hemophilia who have received clotting factor concentrates;
- persons who have traded sex for money or drugs in the preceding five years;
- persons who have had sex in the past year with someone described in the above categories;
- persons who have been directly exposed in the preceding year to known or suspected HIV-, HBV- or HCV-infected blood;
- current correctional institution inmates or individuals who have been incarcerated for 72 consecutive hours in the preceding year;
- persons who, within the preceding year, have undergone tattooing or ear or body piercing with shared instruments; and
- persons who have had close contact within the preceding year with another person having clinically active hepatitis.

However, sections 40 and 41 of the regulations allow for "exceptional distribution" and permit the use of organs from donors who would fall under the exclusionary criteria under certain conditions, including an informed consent from the recipient and the placement of a copy of the notice of exceptional distribution in the records of both the establishment that distributes the organs and the establishment that transplants them.

5 INITIATIVES AND POLICIES INTENDED TO BOOST ORGAN DONOR RATES

5.1 Registries

Containing information about donors and recipients, a national registry can help authorities to identify who is willing to provide an organ or who requires one. While a database of donors might be helpful in identifying greater numbers of donors, a transplant recipient database can help to improve efficiency in identifying compatible recipients.

Some factors may affect the usefulness of a donor registry that helps to identify individuals who have expressed their intent to donate their organs should they become candidates. These include the efficiency of coordinators in recruiting candidate donors who are registered, the administrative burden of maintaining the registry, and the role of family consent.

Another limiting factor for both the donor and waiting list registries is geography. The viability of retrieved organs is measured in hours and the faster an organ can be transplanted, the better the chances are for a successful outcome. For example, transplantation should occur within eight hours for a liver or a pancreas, four hours for a heart, and two hours for a double heart and lung transplant. The time constraint limits recipient possibilities in a large country, like Canada, which do not exist in smaller countries, like Spain.

Several types of registry are described below.

5.1.1 Databases of Intended Donors

Also referred to as a donor registry, a database of intended donors is what most people have in mind when they discuss a national registry. It refers to a database of names or other identifying information of individuals who have registered their intent to donate one or more organs and tissues after death. The registry can be set up to register consent to donate only or, as is the case in Australia, to register either consent or refusal to become a donor.

While there is no national database in Canada, all provinces and territories provide some means of registering intent to donate, listed below.

British Columbia: BC Transplant's Organ Donor Registry allows residents to register their intent online to become donors or not to become donors.[24]

Alberta: The Alberta Organ and Tissue Donation Registry permits residents to register, edit and update their consent online to donate.[25]

Saskatchewan: The province does not operate a registry. Rather, residents can request a sticker to place on their health card to identify them as intended donors.[26]

Manitoba: Through Transplant Manitoba's Sign Up for Life.ca, residents can register, as well as check and update their consent to donate, online.[27]

Ontario: The Trillium Gift of Life Network operates an organ and tissue donor registry. Residents can register, as well as check and update their consent to donate, online.[28]

Quebec: Quebec's Régie de l'assurance maladie du Québec operates a donor registry. Residents can register their intent to donate online or by affixing a signed sticker to their health cards.[29]

New Brunswick: There is no online organ donor registry in New Brunswick. Instead, residents can indicate their desire to become donors when they update or renew their provincial health insurance cards.

Nova Scotia: There is no online organ donor registry in the province. Instead, residents can complete a form that can be mailed or faxed to the Nova Scotia health department's organ donation program.[30]

Prince Edward Island: There is no online registration in the province, but residents may register whether they intend to donate by completing a form and submitting it to the Prince Edward Island medicare office.[31]

Newfoundland and Labrador: There is no online registry in the province, but residents can indicate and update their intent to donate on Medical Care Plan applications for health coverage. Once a resident registers, the words "organ donor" appear on the newly issued health card.[32]

Yukon, Northwest Territories and Nunavut: Residents can complete a form and submit it to the territorial health insurance office to register their intent to donate. In addition to being added to the registry, intended donors receive a sticker to put on their health cards.[33]

A national donor registry could be created through the voluntary participation of the provinces by combining provincial databases into a single registry. However, provinces could argue that this approach would encroach on their jurisdiction, and it might create a cumbersome and costly system.

At any rate, creating a national donor base in this way would not necessarily result in higher organ donor rates. Without an awareness and education campaign, a database, voluntary or otherwise, might be undermined by such factors as the withholding of family consent and the belief among many that if consent is granted before their deaths, less effort will be put into saving their lives. This latter perception may explain the discrepancy between the high proportion of people who say they support organ donation and the low percentage of individuals who sign their donor cards.

5.1.2 National Real-Time Waiting Lists for Patients Requiring Transplants

Proponents of real-time wait lists sometimes point to the registry operated in the United States as an example to follow. When an organ donor has been identified and consent obtained in the U.S., the procuring organization accesses the national transplant computer system operated by the OPTN, either online or by contacting the UNOS Organ Center directly, to enter donor information, and a donor–recipient search for a match is run for each donated organ. The resulting list of potential recipients is ranked according to objective medical criteria (e.g., blood type, tissue type, and size of the organ, as well as medical urgency of the patient's situation, time already spent on the waiting list and distance between donor and recipient). Each organ has its specific criteria.

Using the list of potential recipients, the local organ procurement coordinator or an organ placement specialist contacts the transplant centre of the highest-ranked patient and offers the organ. If the organ is turned down, the organ procurement coordinator or placement specialist contacts the transplant centre for the next potential recipient on the match list. Once the organ is accepted for a patient, UNOS assists with the transportation arrangements, and the transplant surgery is scheduled.[34]

As mentioned above, Canada does not have a centralized list of all patients waiting for an organ. However, since accepting responsibility for Canada's organ and tissue donation and transplantation system, Canadian Blood Services has developed, with the participation of all jurisdictions, including Quebec, the Canadian Transplant Registry. It consists of three national patient registries, described below.

5.1.2.1 Kidney Paired Donation Program

On 24 June 2009, Canadian Blood Services announced the first kidney transplants performed through the Living Donor Paired Exchange (LDPE), the first registry of its kind in Canada. The LDPE, which is both a donor and a recipient registry, aims to optimize the use of kidneys from living donors. It registers pairs of individuals: a willing donor and a needy recipient looking for another donor/recipient pair where tissue type and blood group make "swapping" possible. If an individual is willing to donate a kidney to a certain recipient but is not a match for that recipient, the donor may register and possibly be a match for another recipient. In 2014, the program was renamed the Kidney Paired Donation (or KPD) Program. Between 2009 and 2017, the KPD Program facilitated 543 kidney transplants.[35]

5.1.2.2 National Organ Waitlist

The National Organ Waitlist (NOW) was launched in June 2012. NOW is a real-time, online listing of Canadians awaiting transplant for all organs except kidneys (heart, lung, liver, pancreas and bowel, or multiple organs). Provincial and territorial donation and transplantation programs can access the secure database to identify patients in the most critical need anywhere in Canada. NOW alerts are also sent regularly to health care subscribers to provide information about wait times and organ availability.[36]

5.1.2.3 Highly Sensitized Patient Program

The Highly Sensitized Patient (HSP) program was launched in fall 2013 as a cooperative effort of the provincial transplant programs to provide kidneys for donation to patients whose immune systems are highly sensitized. It provides a registry for kidney transplant candidates who are difficult to match and includes efforts to help find donors for these highly sensitized patients through national sharing. Since 2013, the HSP Program has facilitated 368 kidney transplants.[37]

5.1.3 Living Donor Registry

Canadian Blood Services operates the OneMatch Stem Cell and Marrow Registry, which is a registry of potential live donors of bone marrow or circulating peripheral blood (both sources of stem cells) for all provinces except Quebec. In Quebec, Héma-Québec operates the Stem Cell Donor Registry.[38] Both registries are part of the international Bone Marrow Donors Worldwide network, which provides access to 25 million potential donors around the world.[39]

5.2 Cord Blood Bank

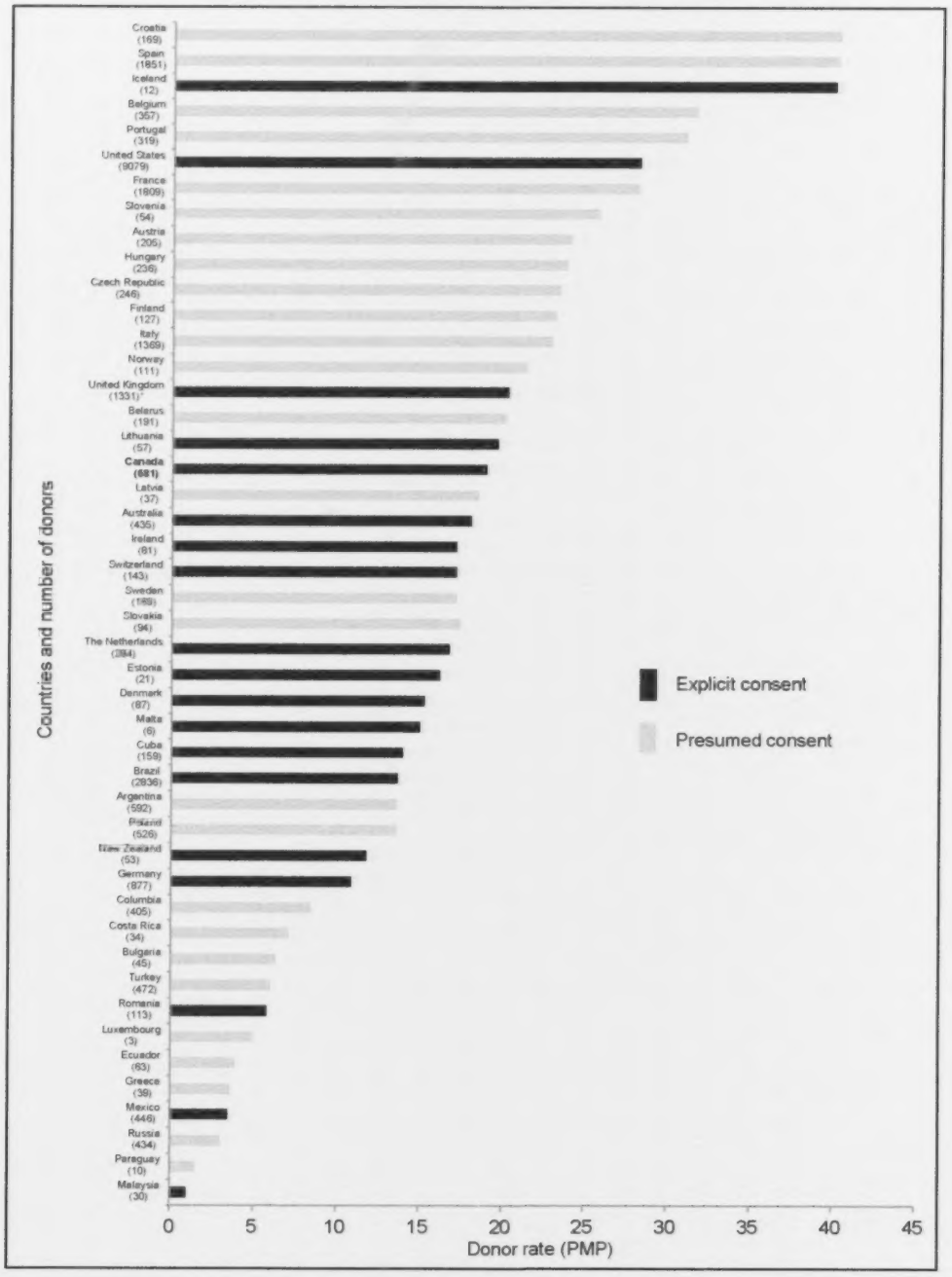
Umbilical cord blood is a rich source of stem cells, which are used in the treatment of blood disorders such as aplastic anemia and leukemia. Stem cell transplants from cord blood result in less tissue rejection than stem cell transplants from other sources. On 14 March 2011, the provincial and territorial ministers of health (except Quebec's minister) announced that they would together fund a national public umbilical cord blood bank, to be created and managed by Canadian Blood Services. The Cord Blood Bank now includes multiple collection and storage facilities.[40] Héma-Québec has created a provincial public cord blood bank.[41]

5.3 Presumed Consent

Another option often suggested as a way to increase the donor rate is presumed consent, sometimes called the opt-out system. Under this approach, consent to donate is presumed unless a person has expressly indicated otherwise during his or her lifetime. In Canada, all provinces and territories operate opt-in, or "explicit consent" or "required consent," systems, whereby an individual expresses the intention to become a donor. Consent to donate is addressed under the provincial and territorial statutes pertaining to organ and tissue donation.[42] Failure to express a desire to donate during one's lifetime is not considered a refusal to become a donor – the family becomes the ultimate source for consent. Proponents of the presumed consent approach note that the vast majority of Canadians are in favour of organ donation when asked but that only a fraction of those who are in favour actually register their intent in a database or through their health cards.[43]

Many countries have adopted the presumed consent approach, and proponents of this approach note that the majority of countries with the highest deceased donor rates worldwide have established presumed consent legislation.[44] Figure 5 shows deceased organ donor rates and consent regimes for selected countries.

Figure 5 – Deceased Organ Donor Rates (per million population), Consent Regimes and Number of Donors in Selected Countries, 2015



Note: * Explicit consent to donate organs is required in the United Kingdom, with the exception of Wales, which operates a presumed consent system.

Source: Figure prepared by the Library of Parliament using data obtained from Global Observatory on Donation and Transplantation, *Organ Donation and Transplantation Activities, 2015*, September 2017.

At the same time, several countries with presumed consent regimes have donor rates that are lower than some countries that operate opt-in systems. For example, Poland and Sweden, which both have presumed consent legislation, report lower donor rates than Canada under its opt-in approaches. The United States, the United Kingdom and Ireland, which are among the countries with the highest donor rates, have opt-in systems.[45]

A review of studies that compared donation rates before and after the introduction of legislation for presumed consent in three countries found that presumed consent "is associated with increased organ donation rates, even when other factors are accounted for."[46] The review's authors noted, however, that there was little examination in the studies of any other changes taking place when the legislation was introduced, and that other factors, such as the availability of donors, the infrastructure of the transplantation service, investment in health care, and public attitudes to organ donation may all have played a role in determining donor rates.

This conclusion is supported by analyses of organ donor rates in both Spain and Brazil, which suggest that it was not the introduction of presumed consent legislation per se that brought about an increase in organ donor rates, but rather an increased investment in donation and transplantation infrastructure. Spain, which has had the highest organ donor rate worldwide for several years, did not realize an improvement in the organ donor rate despite its presumed consent system until the country invested in organ donation infrastructure.[47] Brazil abolished its presumed consent law shortly after implementing presumed consent in the late 1990s, when it realized that without the added infrastructure, presumed consent would not produce additional organ donors.[48]

Other countries have taken different approaches to rendering presumed consent more effective. Singapore, Israel and Chile, for example, have implemented policies whereby individuals who opt out as potential organ donors under their presumed consent systems are given lower priority should they need an organ transplant.[49]

It has been reported that few countries that have presumed consent legislation actually enforce it.[50] Rather, these jurisdictions have brought about improved organ donor rates by addressing family consent and donor identification and recruitment.[51] Awareness campaigns that reinforce the need to voice one's intentions to family, as well as professional awareness and training programs that ensure donor identification and recruitment occur under a specific set of guidelines and policies, are some of the actions taken by high-performing countries to improve organ donor rates.

A 2012 article about the deceased donation process in 29 countries where explicit consent must be given and 25 countries operating presumed-consent systems observed that "deceased donation programs are complex, affected not only by law, administration and infrastructure but also ideology and values. It is improbable that any single strategy or approach will cause a marked improvement on deceased donation rates."[52] The article asserts that the authority of next of kin must be factored into any decision to implement presumed consent.

5.4 Mandatory Referral

Mandatory referral (or required reporting) is the requirement that health care professionals report all brain deaths (and possibly cardiac deaths) or imminent deaths to their local organ procurement organization. With the exception of Saskatchewan and Newfoundland and Labrador, all provinces have implemented or are implementing some sort of mandatory referral system in an effort to boost donor rates.[53]

5.5 Professional Training in Donor Recruitment

In the past, health care professionals were not given specific training for recruiting organ donors. As a result, they may have felt reluctant to approach the families of potential donors and may not have been adequately informed about organ referral. Over the years, as organ donation and transplantation programs have evolved, specially trained organ donor coordinators and physicians have joined these programs. The coordinators are trained to identify potential donors and approach families for consent. The organ donor physicians are trained to improve donation practices, support donor care, and facilitate education and awareness, all in collaboration with the coordinators and the health care facility. British Columbia, Manitoba and Ontario have implemented donation physician programs, and many other provinces are in the process of developing such programs.[54] Canadian Blood Services describes the inclusion of donation physicians as the "cornerstone" of Spain's successful organ donation and transplantation program.[55]

5.6 Mandatory Declaration

Mandatory declaration (sometimes referred to as "required request") ties consent for organ donation to a regulated program, usually provincial health care coverage, for which every resident applies. This approach requires that, as part of the application process, individuals declare whether or not they consent to organ donation following death.

5.7 Public Awareness

A key component of the national donation and transplantation strategy that was recommended in the 1999 reports of the House of Commons Standing Committee on Health and of Health Canada was the introduction of a national public awareness campaign. The aims of such a campaign would be to enable informed choice and to increase support for and participation in the donation and transplantation process.

To date, no national public awareness campaign has been launched in Canada, but many organ donation organizations, charities and advocacy groups have run campaigns to promote organ donation and transplantation. In addition, Canadian Blood Services, after assuming responsibility in 2008 for organ and tissue donation, held public dialogue sessions across Canada and continues to provide information kits on how to initiate and facilitate family discussions on organ donation.

6 CONCLUSION

Canada's deceased organ donor rate has increased in recent years, thanks in large part to provincial efforts, such as the introduction of dedicated donation practitioners, required referral of potential donors, donation after circulatory determination of death, and improved recruitment of donors following cardiorespiratory death. However, the demand for organs still is not met, and Canadian organ donor rates lag behind those of many countries. While recruitment of living donors has been more successful, primarily for kidney donation but also for partial liver donation, the living organ donor rate has not risen significantly in the last 10 years.

Efforts to improve the donation and transplantation system increased after 2008, when responsibility for coordinating national efforts in organ donation and transplantation was transferred to Canadian Blood Services. Since that time, Canada has seen more transplant activity, thanks to the Kidney Paired Donor Program and the real-time transplant waiting lists through the Highly Sensitized Patient Registry and the National Organ Waitlist.

Debate continues in Canada and other countries about whether the introduction of a presumed consent regime, whereby consent to donate is presumed unless a person has expressly indicated otherwise during his or her lifetime, would increase organ donor rates. Many countries that have introduced such legislation have seen increases in donor rates, but generally only when concurrent investments in donation and transplantation infrastructure have also been made.

NOTES

* This paper is the revised version of the publication of the same name by the same author: Sonya Norris, *Organ Donation and Transplantation in Canada*, Publication no. 2011-113-E, Parliamentary Information and Research Service, Library of Parliament, Ottawa, 21 November 2014.

1. House of Commons, Standing Committee on Health, *Organ and Tissue Donation and Transplantation: A Canadian Approach*, 1st Session, 36th Parliament, April 1999; and National Coordinating Committee for Organ and Tissue Donation, Distribution and Transplantation, *A Coordinated and Comprehensive Donation and Transplantation Strategy for Canada*.
2. Canadian Blood Services, "Organ donation and transplantation streamlined in new national system – Patient/donor registries and $35 million in new funding will save lives," News release, *Cision*, 12 August 2008.
3. Please see the Transplant Québec website.
4. Brain death refers to the total cessation of brain function as manifested by the absence of consciousness, spontaneous movement, absence of spontaneous respiration and absence of all brain stem functions.
5. Canadian Organ Replacement Register [CORR] of the Canadian Institute for Health Information [CIHI], "Annual Statistics on Organ Replacement in Canada: Dialysis, Transplantation and Donation, 2007 to 2016," *CIHI Snapshot*, December 2017, p. 2.

6. CIHI, "Organ donations continue to fall short of meeting demand," News release, 17 March 2016.
7. CIHI, "Table 2: Mean Number of Organs Transplanted per Deceased Donor by Age Group, Canada, 1999 to 2008," *Organ Donor Activity in Canada, 1999 to 2008*, "Analysis in Brief" series, 22 December 2009, p. 10.
8. CIHI CORR, "Table 4: Deceased Organ Donor, by Province/Region Identifying Donor, Canada (Number)," *2012 E-Statistics Report On Transplants, Waiting Lists And Donors*.
9. CIHI CORR, *Canadian Organ Replacement Register Annual Report: Treatment of End-Stage Organ Failure in Canada, 2003 to 2012*, 2014.
10. CIHI CORR, "Figure 23, Donor rate per million population, by donor source, Canada, 2007 to 2016," "Treatment of End-Stage Organ Failure in Canada, Canadian Organ Replacement Register, 2007 to 2016: Data Tables, Donors," *CORR Annual Statistics, 2007 to 2016*.
11. International Registry in Organ Donation and Transplantation, *Final Numbers 2016*, December 2017.
12. Ibid.
13. See World Health Organization, *Global Glossary of Terms and Definitions on Donation and Transplantation*, November 2009; and United States, Organ Procurement and Transplantation Network, "Policy 1: Administrative Rules and Definitions," *Policies*.
14. CIHI, *Deceased Organ Donor Potential in Canada*, December 2014, p. 18.
15. Vivek Rao et al., "Effect of organ donation after circulatory determination of death on number of organ transplants from donors with neurologic determination of death," *CMAJ* [Canadian Medical Association Journal], Vol. 189, No. 38, 25 September 2017.
16. Sam D. Shemie et al., "Donation after cardiocirculatory death in Canada," *CMAJ*, Vol. 175, No. 8 (supplement), 10 October 2006.
17. CIHI CORR (December 2017).
18. CIHI (22 December 2009), p. 10.
19. United Network for Organ Sharing [UNOS] originated in 1977 as the South-Eastern Organ Procurement Foundation and developed the first computerized system for matching organs to recipients. In 1984, UNOS was incorporated as an independent, non-profit organization.
20. According to UNOS, "equity basis" refers to the principle that compatible transplant candidates have an equitable chance of receiving a transplant according to appropriate medical criteria. Candidates for deceased donor organs are prioritized for organ offers only on the basis of medical and logistical characteristics, not on personal/social/economic factors such as wealth, underlying cause of organ failure and celebrity status.
21. CIHI CORR (December 2017).
22. Health Canada, "Fact Sheet: Safety of Cells, Tissues and Organs (CTO) for Transplantation," News release, 28 January 2008.
23. *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*, SOR/2007-118. For other background information, see Government of Canada, *Cells, Tissues and Organs*.
24. BC Transplant, *Register Your Decision!*
25. MyHealth.Alberta.ca, *Alberta Organ and Tissue Donation Registry*.
26. Canadian Transplant Society, *Saskatchewan Organ and Tissue donation*.

27. Winnipeg Regional Health Authority, *Sign Up for Life.ca*.

28. Trillium Gift of Life Network, *BeADonor.ca*.

29. Santé et Services sociaux Québec, *Signez don!*

30. Nova Scotia, Department of Health and Wellness, *Organ and Tissue Donation – Giving Life*.

31. Prince Edward Island, *Register as an Organ and/or Tissue Donor*.

32. Newfoundland and Labrador, Department of Health and Community Services, "Medical Care Plan (MCP)," *Forms and Applications*.

33. Yukon, Health and Social Services, *Organ donation program*.

34. This information was obtained from the UNOS and the U.S. Department of Health and Human Services Organ Procurement and Transplantation Network websites.

35. Canadian Blood Services, *Kidney Paired Donation (KPD) Program*.

36. Canadian Blood Services, *National Organ Waitlist (NOW)*.

37. Canadian Blood Services, *Highly Sensitized Patient (HSP) Program*.

38. Héma-Québec, *Stem cells*.

39. Canadian Blood Services, "International marrow registries together reach 25 million donor milestone," News release, 23 March 2015.

40. Canadian Blood Services, "Canadian Blood Services' Cord Blood Bank is now officially launched," News release, 25 June 2015.

41. Héma-Québec, *Umbilical Cord Blood Donation*.

42. British Columbia, *Human Tissue Gift Act*, R.S.B.C. 1996, c. 211; Alberta, *Human Tissue and Organ Donation Act*, S.A. 2006, c. H-14.5; Saskatchewan, *The Human Tissue Gift Act*, R.S.S. 1978, c. H-15; Manitoba, *The Human Tissue Gift Act*, C.C.S.M. 1987, c. H180; Ontario, *Trillium Gift of Life Network Act*, R.S.O. 1990, c. H.20; Quebec, *Civil Code of Québec*, c. CCQ-1991, art. 25; New Brunswick, *Human Tissue Gift Act*, R.S.N.B. 2014, c. 113; Nova Scotia, *Human Tissue Gift Act*, R.S.N.S. 1989, c. 215; Prince Edward Island, *Human Tissue Donation Act*, R.S.P.E.I. 2011, c. H-12.1; Newfoundland and Labrador, *Human Tissue Act*, R.S.N.L. 1990, c. H-15; Yukon, *Human Tissue Gift Act*, R.S.Y. 2002, c. 117; Northwest Territories, *Human Tissue Donation Act*, S.N.W.T. 2014, c. 30; and Nunavut, *Consolidation of Human Tissue Act*, R.S.N.W.T. 1988, c. H-6.

43. Canadian Transplant Society, "Facts."

44. Sonya Norris, *Consent for Organ Donation in Canada*, HillNotes, Library of Parliament, 23 January 2018.

45. Global Observatory on Donation and Transplantation, "Donation from deceased persons. Absolute numbers and rates (pmp). 2015," *Organ Donation and Transplantation Activities, 2015*, Slide 9.

46. Amber Rithalia et al., "Impact of presumed consent for organ donation on donation rates: a systematic review," *BMJ* [British Medical Journal], Vol. 338, 2009, p. 7.

47. R. Matesanz et al., "How Spain Reached 40 Deceased Organ Donors per Million Population," *American Journal of Transplantation*, Vol. 17, No. 6, June 2017.

48. Claudio Csillag, "Brazil abolishes 'presumed consent' in organ donation," *The Lancet*, Vol. 352, Issue 9137, 24 October 1998.

49. Alejandra Zúñiga-Fajuri, "Increasing organ donation by presumed consent and allocation priority: Chile," *Bulletin of the World Health Organization*, Vol. 93, No. 3, March 2015.

50. Simon Bramhall, "Presumed consent for organ donation: a case against," *Annals of the Royal College of Surgeons of England*, Vol. 93, No. 4, May 2011.

51. Rithalia (2009).

52. Amanda M. Rosenblum et al., "The authority of next-of-kin in explicit and presumed consent systems for deceased organ donation: an analysis of 54 nations," *Nephrology Dialysis Transplantation*, Vol. 27, No. 6, June 2012.

53. Canadian Blood Services, "Figure 9: Factors contributing to higher donation rates," *Organ Donation and Transplantation in Canada: System Progress Report 2006–2015*, 2016, p. 27.

54. Ibid., p. 25.

55. Ibid., p. 55.